

REMARKS

Reconsideration and withdrawal of the restriction requirement and election of species are respectfully requested in view of the remarks herein.

The July 16, 2003 Office Action required restriction from among:

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| Group I | Claims 1-39, drawn to a method of non-invasive genetic immunization in an animal, classified in class 514, subclass 44; |
| | and |
| Group II | Claims 1-39, drawn to a method of inducing a systemic immune response to a gene product, classified in class 514, subclass 44. |

The claims have been amended herein, canceling claims 2, 5, 18, 19, 27, 33 and 34, amending claims 3, 4, 6, 14 and 20, and adding claim 40, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents. It is believed that new claim 40 may also be also be placed in both Groups I and II, such that Applicants elect, with traverse, the claims of Group I, i.e. claims 1, 3, 4, 6-17, 20-26, 28-32 and 35-40.

Additionally, the Office Action required the election of a single bacterial vector to be used as set forth in claims 5 and 6. The bacterial vectors originally presented in claims 5 and 6 are now present only in claim 6, claim 5 having been cancelled herein. Accordingly, it is believed that the amendments herein necessitate no amendment to the species election requirement, and Applicants elect, with traverse, the bacterial vector *Escherichia*. Should the species election stand, the election of *Escherichia* will read on pending claims 1, 4, 6, 9-17, 20-26, 28-32 and 35-40.

The MPEP lists two criteria for a proper restriction requirement. First, the invention must be independent or distinct. MPEP § 803. Second, searching the additional invention must constitute an undue burden on the examiner if restriction is not required. *Id.* The MPEP directs the examiner to search and examine an entire application “ [i]f the search and examination of an entire application can be made without serious burden, ... even though it includes claims to distinct or independent inventions.” *Id.*

The Office Action states that the “inventions are distinct ... because ... Inventions I and II are unrelated.” Office Action at 2. In the instant application, the claims of Groups I and II allegedly are drawn to two different methods which result in two materially different outcomes.

It is respectfully submitted that the identical classification of Groups I-II contradicts this statement.

It is again respectfully submitted that MPEP § 803 directs the examiner to search and examine an entire application “[i]f the search and examination of an entire application can be made without serious burden, ... even though it includes claims to distinct or independent inventions.” *Id.*

The Office Action maintains that the Groups are independent inventions, but, it is respectfully submitted, does not provide an adequate demonstration that the examination of more than one Group would present an undue burden on the Examiner. Again, the claims of Groups I and II are all classified in class 514, subclass 44, demonstrating that the claims of Groups I and II constitute a web of knowledge and that searching one Group would necessarily be co-extensive with the other Groups.

In view of the above, reconsideration and withdrawal of the restriction requirement is respectfully requested.

Furthermore, the Examiner is respectfully requested to review M.P.E.P. § 808.01(a), which states that “where there is no disclosure of relationship between species (*see* M.P.E.P. §806.04 (b)), they are independent inventions and election of one invention” is required. In view of M.P.E.P. §803, however, when the generic claim includes sufficiently few species that a search and examination of all the species at one time would not impose a serious burden on the examiner, then a requirement for election is inappropriate.

In the instant case, there is a disclosure of relationship between the claimed species. Applicants’ claims are directed to, *inter alia*, a method of non-invasive genetic immunization or of inducing a systemic immune response to a gene product, in an animal, comprising contacting skin of the animal with a bacterial vector that contains and expresses a nucleic acid molecule encoding the gene product, in an amount effective to induce the response. The bacterial vectors described in claim 6 are claimed in the methods described above. Consequently, there is a disclosed relationship between the bacterial vectors.

Additionally, the claims are not broken into separate classifications on the basis of which bacterial vector is claimed. Consequently, it can be assumed that the classification of all the claims (and specifically claims 5 and 6 as originally presented) into class 514, subclass 44 was made considering each of the bacterial vectors, such that the search of any bacterial vector would

be co-extensive and include the remaining bacterial vectors. Furthermore, the Office Action has made no showing that searching the bacterial vectors of claim 6 would constitute an undue burden. Consequently, it is respectfully submitted that the requirement for an election of species is inappropriate.

In view of the above, reconsideration and withdrawal of the election of species requirement are requested.

In summary, enforcing the present restriction and election requirements would result in inefficiencies and unnecessary expenditures by both the Applicants and the PTO, as well as extreme prejudice to Applicants (particularly in view of GATT, whereby a shortened patent term may result in any divisional applications filed). Restriction has not been shown to be proper, especially since it has been shown that the requisite showing of serious burden has not been made. Indeed, the search and examination of each Group would be likely to be co-extensive and, in any event, would involve such interrelated art that the search and examination of the entire application can be made without undue burden on the Examiner, especially as the claims of all Groups have identical classifications. Furthermore, the election requirement has not been shown to be proper, especially since, *inter alia*: 1) the requisite showing of serious burden has not been made in the Office Action; and, 2) there are relationships among the bacterial vector species. All of the preceding, therefore, mitigate against restriction.

Consequently, reconsideration and withdrawal of the restriction and election of species requirement are respectfully requested.

CONCLUSION

In view of the amendments, and remarks herein, reconsideration and withdrawal of the restriction requirement and election of species is respectfully requested. Applicants respectfully request an early and favorable examination on the merits.

Respectfully submitted,

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